IB00/00530

Sertifikaat

REPUBLIEK VAN SUID-AFRIKA

PATENTKANTOOR

DEPARTEMENT VAN HANDEL EN NYWERHEID

Certificate

REPUBLIC OF SOUTH AFRICA

PATENT OFFICE

DEPARTMENT OF TRADE AND INDUSTRY

4

Hiermee word gesertifiseer dat
This is to certify that the documents annexed hereto are true copies of:

Application forms P.1 and P.3, provisional specification and drawings of South African Patent Application No. 99/3006 as originally filed in the Republic of South Africa on 29 April 1999 in the name of PETER JAMES BRIAN LAMB for an invention entitled: "DEVICE FOR DEPOSITING A NON-FLOWABLE MEDICAMENT IN A BODY CAVITY".

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

REC'D 29 MAY 2000
WIPO PCT

te PRETORIA in die Republiek van Suid-Afrika, hierdie 3rd dag van May 2000
in the Republic of South Africa, this day of

Registrateur van Patente
Registrar of Patents

REPUBLIC OF SOUTH AFRICA
PATENTS ACT, 1978
APPLICATION FOR A PATENT AND
ACKNOWLEDGEMENT OF RECEIPT
(Section 30(1) Regulation 22)

REPUBLIC OF SOUTH AFRICA
FORM P.1 REVENUE
(to be lodged in duplicate)

29.4.99 R 060.00

REPUBLIEK VAN SUID AFRIKA
A&A REF: JAV/13358/0

THE GRANT OF A PATENT IS HEREBY REQUESTED BY THE UNDERMENTIONED APPLICANT ON THE BASIS OF THE PRESENT APPLICATION FILED IN DUPLICATE

21	01	PATENT APPLICATION NO	993006

71 FULL NAME(S) OF APPLICANT(S)

PETER JAMES BRIAN LAMB

REGISTRAR OF PATENTS, TRADE MARKS AND COPYRIGHT
PRIVATE BAG/PRIVAATSAK X400
1999 -04- 29
PRETORIA 0001
REGISTRATEUR VAN PATENTE, MODELLE, HANDELSMERKE EN OUTEURSREG

ADDRESS(ES) OF APPLICANT(S)

12 Clifford Road, IRENE, 1675, Republic of South Africa

54 TITLE OF INVENTION

"DEVICE FOR DEPOSITING A NON-FLOWABLE MEDICAMENT IN A BODY CAVITY"

Only the items marked with an "X" in the blocks below are applicable.

[ ] THE APPLICANT CLAIMS PRIORITY AS SET OUT ON THE ACCOMPANYING FORM P.2. The earliest priority claimed is
Country: No: Date:

[ ] THE APPLICATION IS FOR A PATENT OF ADDITION TO PATENT APPLICATION NO 21 01

[ ] THIS APPLICATION IS A FRESH APPLICATION IN TERMS OF SECTION 37 AND BASED ON APPLICATION NO 21 01

THIS APPLICATION IS ACCOMPANIED BY:

X	A single copy of a provisional specification of 10 pages
X	Drawings of 1 sheets
	Publication particulars and abstract (Form P.8 in duplicate) (for complete only)
	A copy of Figure of the drawings (if any) for the abstract (for complete only)
	An assignment of invention
	Certified priority document(s). (State quantity)
	Translation of the priority document(s)
	An assignment of priority rights
	A copy of Form P.2 and the specification of RSA Patent Application No 21 01
X	Form P.2 in duplicate
X	A declaration and power of attorney on Form P.3
	Request for ante-dating on Form P.4
	Request for classification on Form P.9
	Request for delay of acceptance on Form P.4
	Extra copy of informal drawings (for complete only)

74 ADDRESS FOR SERVICE: Adams & Adams, Pretoria

Dated this 29 day of April 1999

ADAMS & ADAMS
APPLICANTS PATENT ATTORNEYS

The duplicate will be returned to the applicant's address for service as proof of lodging but is not valid unless endorsed with official stamp

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OFFICIAL DATE STAMP

A&A P201

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REPUBLIC OF SOUTH AFRICA
PATENTS ACT, 1978
DECLARATION AND POWER OF ATTORNEY
(Section 30 - Regulation 8, 22(i)(c) and 33)

FORM P.3

PATENT APPLICATION NO		
21	01	993006

A&A Ref: V13358 LVDW/tr

LODGING DATE	
22	29 APRIL 1999

FULL NAME(S) OF APPLICANT(S)	
71	PETER JAMES BRIAN LAMB

FULL NAME(S) OF INVENTOR(S)	
72	PETER JAMES BRIAN LAMB

EARLIEST PRIORITY CLAIMED	COUNTRY		NUMBER		DATE	
	33	--	31	--	32	-- --

NOTE: The country must be indicated by its International Abbreviation - see schedule 4 of the Regulations

TITLE OF INVENTION	
54	DEVICE FOR DEPOSITING A NON-FLOWABLE MEDICAMENT IN A BODY CAVITY

* I/We PETER JAMES BRIAN LAMB

hereby declare that :-

1. I/we am/are the applicant(s) mentioned above;

** 2. ~~I/we have been authorized by the applicant(s) to make this declaration and have knowledge of the facts herein stated in the capacity of of the applicant(s);~~

*** 3. the inventor(s) of the abovementioned invention is/are the person(s) named above ~~and the applicant(s) has/have acquired the right to apply by virtue of an assignment from the inventor(s)~~;

4. to the best of my/our knowledge and belief, if a patent is granted on the application, there will be no lawful ground for the revocation of the patent;

**** 5. ~~this is a convention application and the earliest application from which priority is claimed as set out above is the first application in a convention country in respect of the invention claimed in any of the claims;~~ and

6. the partners and qualified staff of the firm of **ADAMS & ADAMS**, patent attorneys, are authorised, jointly and severally, with powers of substitution and revocation, to represent the applicant(s) in this application and to be the address for service of the applicant(s) while the application is pending and after a patent has been granted on the application.

SIGNED THIS 9th DAY OF APRIL 1999

Company Name:
Full Names:
Capacity:

(no legalization necessary)

* In the case of application in the name of a company, partnership or firm, give full names of signatory/signatories, delete paragraph 1, and enter capacity of each signatory in paragraph 2.
** If the applicant is a natural person, delete paragraph 2.
*** If the right to apply is not by virtue of an assignment from the inventor(s), delete "an assignment from the inventor(s)" and give details of acquisition of right.
**** For non-convention applications, delete paragraph 5.

A & A Ref No: V13358

FORM P6

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REPUBLIC OF SOUTH AFRICA
Patents Act, 1978

PROVISIONAL SPECIFICATION

(Section 30 (1) - Regulation 27)

21	01	OFFICIAL APPLICATION NO

993006

22	LODGING DATE

29 April 1999

71	FULL NAME(S) OF APPLICANT(S)

PETER JAMES BRIAN LAMB

72	FULL NAME(S) OF INVENTOR(S)

PETER JAMES BRIAN LAMB

54	TITLE OF INVENTION

"DEVICE FOR DEPOSITING A NON-FLOWABLE MEDICAMENT IN A BODY CAVITY"

THIS INVENTION relates to a device for depositing a non-flowable medicament in a body cavity.

Various conventional devices for depositing a non-flowable medicament, such as a tablet in body cavities, such as the vagina and rectum, exist. Typically, these conventional devices comprises a blunt, straight, hollow tube or barrel into which a plunger or piston can be inserted from one end, with a medicament chamber being provided at an opposed end. All of the conventional devices suffer from at least some of the following problems:

The conventional device is of a hard and non-pliable material so there is no bend or give during insertion of the device into a vagina. This rigidity makes vaginal insertion more difficult and painful. Often women do not know that the vagina is angled upwards from its opening and that it is not horizontal. After inserting a leading end of the conventional device through the vaginal opening in the horizontal direction, the leading end collides with the back wall of the vagina, which is painful and causes the user to think that the device has reached the limit of the vagina. The user then deposits the medicament at a too shallow depth in the vagina. No stop guard is provided to limit the depth of insertion of the conventional devices into the vagina. If the device is inserted to the full depth of the vagina and collides with the vaginal vault, considerable pain is caused. This lack of depth control is particularly hazardous in the case of a pregnant woman. Some conventional devices have leading ends which flare outwards which makes them even more difficult to insert into a vagina. Conventional devices can only comfortably be inserted into a vagina when the

woman is lying on her back with her knees flexed. It is difficult to insert conventional devices which are often difficult to grip and difficult to control when being inserted into a vagina.

It is an object of this invention to provide means which alleviate at least some of these problems.

In accordance with a first aspect of the invention, there is provided a device for depositing a non-flowable medicament in a body cavity, the device including

an elongate body which includes an elongate barrel with a passage, configured to receive the non-flowable medicament, extending through the body, the passage having an outlet at a free end of the barrel, an inlet remote from the outlet and a curved portion between the inlet and the outlet; and

a piston or plunger which can be displaced along the passage to push the medicament out of the passage through the outlet thereof.

The barrel may be penile-shaped at least in cross-section.

According to a second aspect of the invention, there is provided a device for depositing a non-flowable medicament in a body cavity, the device including

an elongate body which includes an elongate barrel with a passage, configured to receive the non-flowable medicament, extending through the body, the passage having an outlet at a free end of the barrel and an inlet remote from the outlet, the barrel being penile-shaped at least in cross-section; and

a piston or plunger which can be displaced along the passage to push to medicament out of the passage through the outlet thereof.

In this specification, the term "non-flowable medicament" is intended to include tablets, capsules, suppositories, pills, bougies, or the like.

The passage of the device according to the second aspect of the invention may have a curved portion between its inlet and its outlet. The passage is typically round in cross-section.

The body of the device may include a gripping portion from which the barrel extends. The inlet of the passage may thus be in the gripping portion, which may be thickened compared to the barrel, thus also functioning in use as a stop formation, limiting the part of the body of the device which may be introduced into a body cavity.

The curved portion of the passage between its inlet and its outlet renders a centrally disposed longitudinal axis of the barrel and a centrally disposed axis through the inlet of the passage at an obtuse angle relative to each other. The obtuse angle may be between 170° and 135°. Preferably, the obtuse angle is between 160° and 140°, and most preferably between 155° and 145°.

An outlet end portion of the barrel may have the general shape or may incorporate at least some of the features of a glans penis. Thus, the barrel may have a rounded point which flares back like the corona of a glans penis and which in use lifts the opposing vaginal walls apart when the barrel is inserted into a vagina. The roughly triangular cross-section of the barrel, similar to that of a penis, allows the smallest area of contact or friction with a posterior vaginal wall. Side walls of the barrel are thus in use angled away from lateral walls of the vagina, with a relatively broad superior wall of the barrel being stabilized by low pressure contact with the anterior vaginal wall.

The outlet of the passage may be in the form of a slit extending between opposed sides of the barrel and may be located in an upper half of the outlet end portion of the barrel.

At least the barrel may be of a material having a Shore A hardness between 40 and 80, e.g. 70. Thus, the barrel may be of a synthetic plastics or polymeric material, such as silicone rubber, having a suitable hardness. The gripping portion may be of a thermoplastic material, with the barrel and the gripping portion being moulded or fused together. Instead, the barrel and the gripping portion may be fitted together by other means, such as glue or mechanical attachment means, thus advantageously allowing the gripping portion to be of a thermoplastic material which has a lower maximum working temperature than the moulding temperature of the material of which the barrel is formed, and which may thus be cheaper. In another embodiment of the invention, the gripping portion and the barrel may both be of the same synthetic or polymeric plastics material, e.g. silicone rubber, the body of the device thus being monolithic and integrally moulded.

The barrel may have a length of between 60mm and 100mm, e.g. 70mm and a maximum external diameter of between 10mm and 20mm, e.g. 17mm.

The piston or plunger may have a flexible rod, allowing the rod to bend to follow the curvature of the passage when it is displaced along the passage. The rod may be of a synthetic plastics or polymeric material, such as polypropylene or the like.

The curved portion of the passage is typically located in the gripping portion of the body, so that the portion of the passage in the barrel is typically linear, allowing at least a portion of the barrel to be straight. Preferably, the entire barrel is straight, which is an advantage, since the human vagina is straight and not curved.

The passage may include a medicament chamber for receiving the non-flowable medicament. The medicament chamber may be spaced from the

outlet of the passage, allowing a part of the barrel, above the outlet, and a part of the barrel, below the outlet, to be displaced or forced towards each other when the barrel is being inserted into a body cavity, thus closing off the outlet whilst the barrel is being inserted into the body cavity and preventing the non-flowable medicament from scraping against or injuring the vaginal mucosa.

The piston or plunger may include a thumb grip at a free end of its rod, the gripping portion of the body defining a recess for the thumb grip so that almost all of the piston or plunger can be received inside the body of the device when the piston or plunger is pushed as far into the passage as it can go.

The invention will now be described, by way of example, with reference to the accompanying diagrammatic drawings in which

Figure 1 is a sectioned side view of an embodiment of a device in accordance with the invention for depositing a non-flowable medicament in a body cavity;

Figure 2 is a top plan view of the device of Figure 1;

Figure 3 is a bottom plan view of the device of Figure 1;

Figure 4 is a front end view of the device of Figure 1; and

Figure 5 is a rear end view of the device of Figure 1.

Referring to the drawings, reference numeral 10 generally indicates an embodiment of a device in accordance with the invention for depositing a non-flowable medicament in a body cavity, such as a vagina. The device 10 includes an elongate monolithic body 12 which comprises an elongate barrel 14 and a gripping portion 16 from which the barrel 14 extends.

The barrel 14 and the gripping portion 16 are integrally moulded from a synthetic plastics or polymeric material such as a silicone rubber and has a Shore A hardness of about 70. A passage 18 extends through the gripping portion 16 and the barrel 14. The passage 18 has an inlet 20 in the gripping

portion 16 and an outlet 22 at a free end of the barrel 14, remote from the gripping portion 16. A portion of the passage 18 between the inlet and the outlet and located in the gripping portion 16, is curved in side view, as can be clearly seen in Figure 1 of the drawings. The passage 18 is round in cross-section.

The curved portion of the passage 18 between its inlet 20 and its outlet 22 renders a centrally disposed longitudinal axis 24 of the barrel 14 and a centrally disposed axis 26 through the inlet 20 of the passage 18, at an obtuse angle of 150° relative to each other (see Figure 1), and this angle thus matches the angle of inclination of the vagina of a standing woman relative to the horizontal.

The barrel 14 is generally penile shaped and is thus roughly triangular in cross-section, similar to the cross section of a penis. More accurately, a cross-sectional outline of the barrel 14 falls on the outline of a triangle. An outlet end portion 28 of the barrel 14, remote from the gripping portion 16, generally has the shape of a glans penis. A bottom surface of the end portion 28 has a sled-like curve in side view to inhibit abrasion of the posterior vaginal wall in use. The barrel 14 thus has a rounded point which flares back like the corona of a glans penis and which in use lifts the opposing vaginal walls apart when the barrel 14 is inserted into a vagina.

The outlet 22 of the passage 18 is in the form of a slit extending between opposed sides of the barrel 14 and is located in an upper half of the outlet end portion 28, to avoid scraping vaginal exudate into the outlet 22 during insertion of the barrel 14 into a vagina in use.

The device 10 includes a piston or plunger 30 which can be displaced along the passage 18 and which includes a flexible rod 32 of polypropylene. The rod 32 is thus able to follow the curvature of the passage

18 when the piston or plunger 30 is displaced along the passage 18. The piston or plunger 30 includes an ergonometrically designed thumb grip 34 at a free end of the flexible rod 32. As can be clearly seen in Figure 1 of the drawings, the gripping portion 16 of the body 12 defines a recess 36 for the thumb grip 34 so that almost all of the piston or plunger 32 can be received inside the body 12 when the piston or plunger 32 is pushed as far into the passage 18 as it can go.

The passage 18 includes or defines a medicament chamber 38 (see Figure 1) for receiving the non-flowable medicament. The medicament chamber 38 is spaced from the outlet 22 of the passage and is in the form of a widening of the passage 18 tailored to receive a tablet or capsule.

Roughened and depressed gripping surfaces 40 are provided on an external top surface and an external bottom surface of the gripping portion 16 of the body 12.

The barrel 14 is approximately 70mm long and has a maximum external diameter of about 17mm.

The device 10 is particularly, though not necessarily exclusively suitable for depositing a non-flowable medicament, such as a tablet or capsule, in a vagina. In use, the piston or plunger is withdrawn from the passage 18 at least far enough so that it does not protrude into the medicament chamber 38, as shown in Figure 1 of the drawings, and the non-flowable medicament is placed inside the medicament chamber by inserting it through the outlet 22. The barrel 14 is then inserted into a body cavity, such as the vagina of a human female until the gripping portion 16 limits the part of the body 12 of the device 10 which can be introduced into the vagina. Thus, the gripping portion 16 also functions in use as a stop formation. The gripping portion 16 affords a large comfortable grip for the hand of the person inserting the barrel 14 into the vagina.

As will be appreciated, since the body 12 is of a silicone rubber and thus quite flexible, a part or upper lip 42 of the barrel 14, above the outlet 22, and a part or lower lip 44 of the barrel 14, below the outlet 22 are displaced or forced towards each other whilst the barrel 14 is being inserted into the vagina. Thus, the outlet 22 is closed off whilst the barrel 14 is being inserted into the vagina, inhibiting intrusion of vaginal exudate into the passage 18 through the outlet 22. The flexibility of the lips 42, 44 also allows for easy insertion of the non-flowable medicament into the medicament chamber 38 and prevents abrasion or injury to the vaginal mucosa by a sharp-edged non-flowable medicament, e.g. a vaginal tablet.

When the barrel 14 is fully inserted into the vagina, the piston or plunger 30 is pushed into the body 12 as far as it can go, forcing the non-flowable medicament out of the medicament chamber 38, through the outlet 22, and thus depositing the non-flowable medicament in the vagina. The barrel 14 is then withdrawn from the vagina.

The Applicant believes that the device 10, as illustrated, and particularly when intended to deposit a non-flowable medicament such as a capsule or tablet in a vagina, has the following advantages:

The length of the barrel 14 is not intimidating, but nonetheless provides effective depth of deposition of the non-flowable medicament. The barrel 14 is of a relatively soft, elastic material which is less difficult and painful to insert than the barrel of conventional devices. The material is easier for the fingers to grip securely and the grippability of the device is further improved by the gripping surfaces 40. The generally triangular, penile-like cross-section of the barrel 14 (see Figure 4) is easier and more comfortable to insert into a vagina. Friction against the back vaginal wall is reduced.

The angular arrangement of the barrel 14 relative to the inlet 20 of the passage 18 promotes easier advancement of the barrel 14 up the vagina. There is a built-in correction for the direction or inclination of the vaginal cavity, which causes less damage and discomfort to the user. The barrel 14 can be inserted whilst the user is sitting or standing and the procedure is therefor much easier and more comfortable to accomplish physically and much less an affront to a female's dignity.

The glans penis-like outlet end portion 28 of the barrel 14 is easier and more comfortable to insert than the leading end portions of conventional devices. The shape and location of the outlet 22 of the barrel 14 provides for better hygiene and promotes comfort when the barrel 14 is inserted into the vagina, by eliminating any scraping effect on the back wall of the vagina.

The thickened gripping portion 16 ensures automatic depth control when the barrel 14 is inserted into a vagina.

The integrally moulded design of the gripping portion 16 and the barrel 14 provides the device 10 with a degree of flexibility, which enhances comfort and ease when the barrel 14 is inserted into a vagina.

The gripping portion 16 provides a large comfortable handle for the device 10. It affords a secure grip and therefor better control of the device 10 during insertion of the barrel 14 into the vagina.

DATED THIS 29TH DAY OF APRIL 1999

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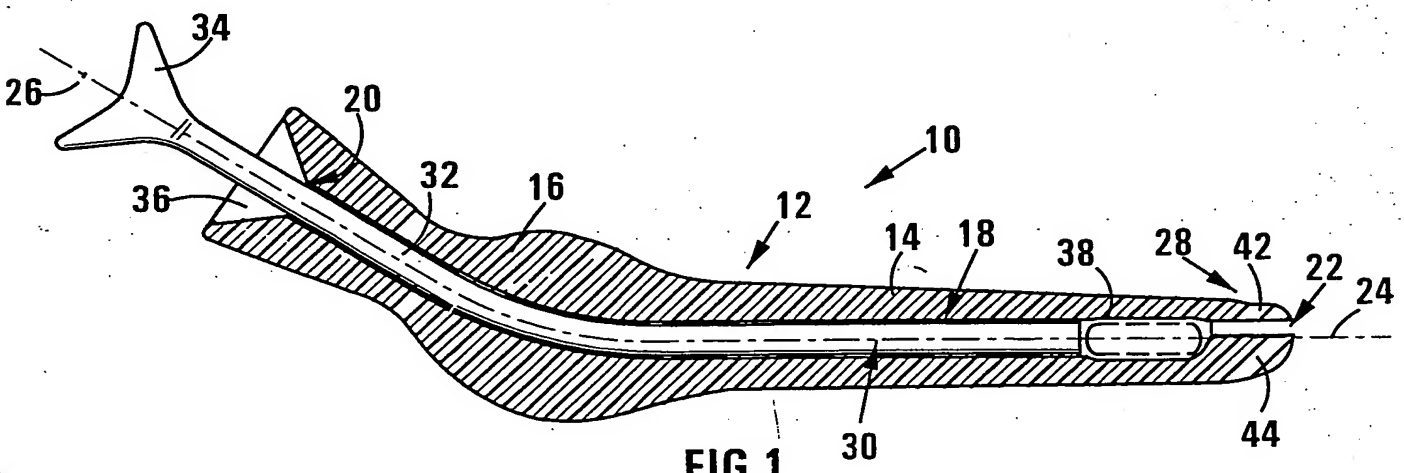

FIG 1

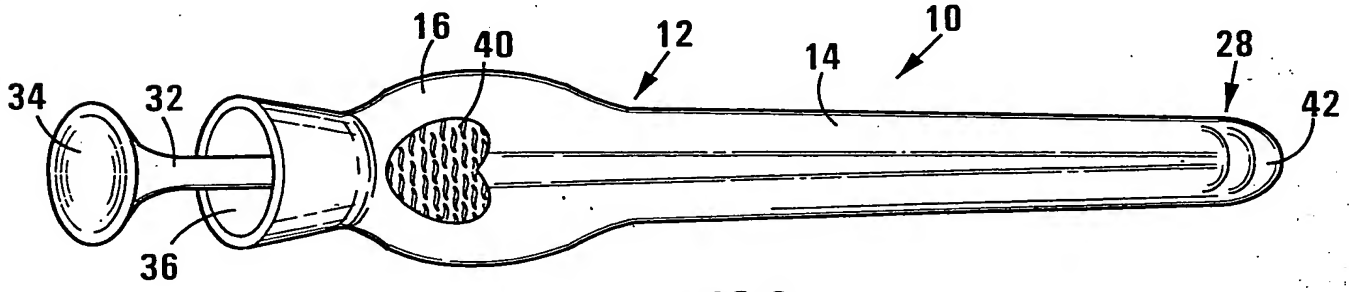

FIG 2

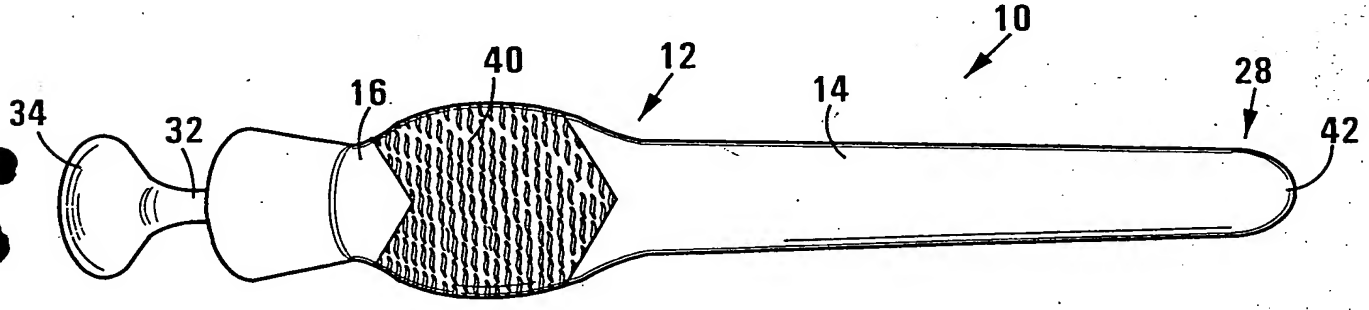

FIG 3

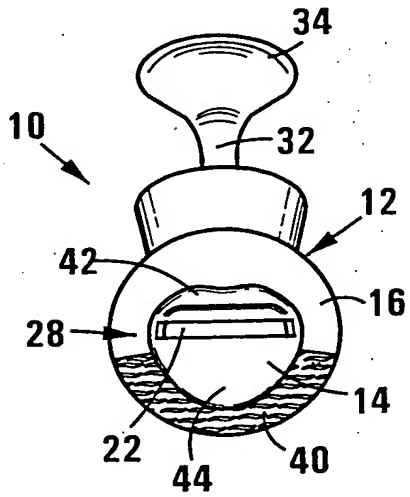

FIG 4

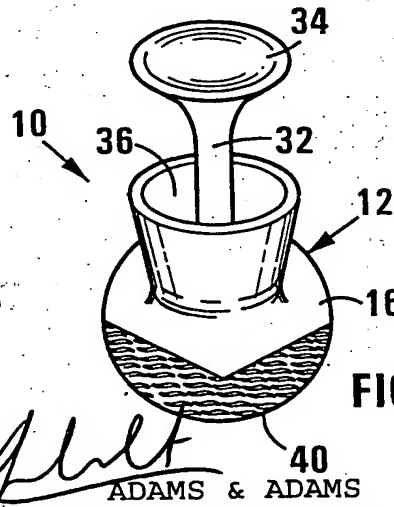

FIG 5

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